



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0161; FRL-9906-99]

Fenamidone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenamidone in or on ginseng; bean, succulent, except cowpea; onion, blub, subgroup 3-07A; and onion, green, subgroup 3-07B. This regulation additionally removes several individual tolerances that are superseded by inclusion in crop subgroup tolerances. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0161, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading

Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0161 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0161, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 5, 2013 (78 FR 33785) (FRL-9386-2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8150) by IR-4, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.579 be amended by establishing tolerances for residues of the fungicide fenamidone, 4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-, in or on ginseng at 0.80 parts per million (ppm); bean, succulent at 0.80 ppm; onion, bulb, subgroup 03-07A at 0.20 ppm; and onion, green, subgroup 03-07B at 1.5 ppm. The petition additionally requested to remove the established tolerances in or on garlic at 0.20 ppm; garlic, great headed at 0.20 ppm; leek at 1.5 ppm; onion, bulb at 0.20 ppm; onion, green at 1.5 ppm; onion, welsh at 1.5 ppm; shallot, bulb at 0.20 ppm; and shallot, fresh leaves at 1.5 ppm, as they will be superseded by the tolerances described in this unit. That

document referenced a summary of the petition prepared on behalf of IR-4 by Bayer CropScience, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that cowpea should not be included in the tolerance in or on bean, succulent. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fenamidone including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenamidone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The target organs in subchronic toxicity studies for fenamidone were generally the liver; rarely, the thyroid or spleen were also affected. Target organs for chronic toxicity studies were the liver in the mouse and dog, and the liver and thyroid in the rat. In the chronic toxicity rat study, diffuse C-cell hyperplasia of the thyroid in both sexes was the most sensitive indicator of toxicity, and at higher doses follicular cells and the liver were also affected. The similarity in the systemic no-observed-adverse-effect-levels (NOAELs) and the type of toxicity observed (primarily liver) for the subchronic rat studies with the parent and plant metabolites (RPA 412636, RPA 412708, and RPA 410193) demonstrated that, on a subchronic basis, plant metabolites were not more toxic than the parent.

In the acute neurotoxicity study in rats, clinical signs included staining of the anogenital region, mucous in the feces, hunched posture, and unsteady gait. In the subchronic neurotoxicity study in rats, marginal decreases in brain weights were observed only in high dose males. Additionally, decreased brain weight occurred in the rat reproduction study. In a developmental neurotoxicity study in Wistar rats, no

neurobehavioral effects and no neuropathological changes were observed at any dose in the offspring, but decreased body weight was observed during pre- and post-weaning.

In prenatal developmental toxicity studies in rabbits and rats, there were no developmental effects up to the highest dose tested (HDT). Maternal toxicity in these studies was observed as increased liver weights in maternal rabbits and decreased body weight gains and food consumption in maternal rats. In the reproduction study in rats, decreased absolute brain weight in F2 female pups occurred at the same dose levels as decreased absolute brain weight in F1 parental females. There were no effects on fertility or other measured reproductive parameters conducted with fenamidone.

An immunotoxicity study in rats showed a potential immunosuppression at the HDT; however, the existing risk assessment points of departure are lower and are therefore protective of this potential effect. No carcinogenic potential was observed in chronic studies in rat, mice, and dog; therefore, EPA has determined that fenamidone is not likely to be a human carcinogen by all relevant routes of exposure. All mutagenicity studies were negative for both the parent and plant metabolites, except the parent induced mutant colonies at the *tk* locus and increased chromosomal aberrations in human peripheral blood.

Specific information on the studies received and the nature of the adverse effects caused by fenamidone as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Fenamidone: Human Health Risk Assessment to Support the Section (3) Registration and the Establishment of Tolerances for Uses on Ginseng, Succulent Beans (Except Cowpea), Bulb Onion (Subgroup 3-07A), and Green Onion (Subgroup 3-07B).” at pp. 30-34 in docket ID number EPA-HQ-OPP-2013-0161.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL of concern are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fenamidone used for human risk assessment is discussed in Unit III.B., Table 1 of the final rule published in the **Federal Register** of November 16, 2011 (76 FR 70890) (FRL-9325-4).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenamidone, EPA considered exposure under the petitioned-for tolerances as well as all

existing fenamidone tolerances in 40 CFR 180.579. EPA assessed dietary exposures from fenamidone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for fenamidone. In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, "What We Eat in America" (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA used maximum field trial residues for plant commodities and residues at the limit of quantitation for livestock commodities, assumed 100 percent crop treated (PCT) estimates for all commodities, and incorporated DEEM™ default processing factors, when applicable.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the same dietary risk assessment assumptions as for the acute dietary risk assessment.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenamidone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use PCT information in the dietary assessment for fenamidone; 100 PCT were assumed for all food commodities. However, anticipated residues were used as maximum field trial residues for plant

commodities and residues at the limit of quantitation for livestock commodities. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data calls as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fenamidone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenamidone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and PRZM Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fenamidone for surface water are expected to be 41.7 parts per billion (ppb) for acute exposures and 11.9 ppb for chronic exposures for non-cancer assessments. For groundwater, the EDWC of 207 ppb is estimated for all acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessments, the water concentration value of 207 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fenamidone is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found fenamidone to share a common mechanism of toxicity with any other substances, and fenamidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenamidone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold

effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicity database for fenamidone includes rat and rabbit developmental toxicity studies, a rat developmental neurotoxicity study (DNT), and a 2-generation reproduction toxicity study in rats. No evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses to *in utero* exposure was observed in the developmental toxicity studies. There was no developmental toxicity in rabbit fetuses up to 100 milligrams/kilograms/day (mg/kg/day), the HDT; maternal toxicity was exhibited as an increase in absolute liver weight, observed at 30 and 100 mg/kg/day. In the rat developmental study, decreased fetal body weight and incomplete fetal ossification were observed, but were considered secondary to maternal toxicity observed as decreased body weight and food consumption at the limit dose (1,000 mg/kg/day). No quantitative or qualitative evidence of increased susceptibility was observed in the 2-generation reproduction study in rats. In that study, both the parental and offspring LOAELs were based on decreased absolute brain weight in female F1 adults and female F2 offspring at 89.2 mg/kg/day. Parental effects consisting of decreased body weight and food consumption and increased liver and

spleen weights were noted at the same level as decreased pup body weight. There were no reproductive effects up to the HDT.

The results of the DNT study indicated an increased susceptibility of offspring. There was no maternal toxicity at the HDT (429 mg/kg/day). Effects in the offspring included decreased body weight (9-11%) and body weight gain (8-20%) during pre-weaning, and decreased body weight (4-6%) during post-weaning at 429 mg/kg/day (LOAEL). There were no neurobehavioral effects and no neuropathological changes at any dose in the offspring.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for fenamidone is complete.
- ii. The concern for the increased susceptibility observed in the DNT is low because:
 - a. There were no neurobehavioral or neuropathological changes in the offspring at any dose;
 - b. A clear NOAEL for the adverse effects in the study was identified; and
 - c. The endpoints used for the various risk assessment scenarios are much more sensitive than that of the decreased bodyweight of the offspring.

Therefore, based on the information above, the available data and the selection of risk assessment endpoints, EPA has determined that all endpoints used in the risk assessment for fenamidone are protective of neurotoxic effects. Accordingly, additional uncertainty factors (UFs) to account for neurotoxicity are not necessary.

iii. There is no evidence that fenamidone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT, maximum field trial residues for plant commodities, and residues at the limit of quantitation for livestock commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenamidone in drinking water. These assessments will not underestimate the exposures and risks posed by fenamidone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenamidone will occupy 4.8% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenamidone from food and water

will utilize 89% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for fenamidone.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, fenamidone is not registered for any use patterns that would result in short- or intermediate-term residential exposures. Short- and intermediate-term risk is assessed based on short- or intermediate-term residential exposure plus chronic dietary exposure. Because there are no short- or intermediate-term residential exposures and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risks are necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risks for fenamidone.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenamidone is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to fenamidone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, a liquid chromatography with tandem mass spectrometry detection (LC/MS/MS), is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for fenamidone.

C. Revisions to Petitioned-For Tolerances

Based on the data supporting the petition, EPA has determined that cowpea should not be included in the bean, succulent tolerance at 0.80 ppm, as was proposed. The bean, succulent definition includes cowpea, and cowpea has forage and hay associated uses that are considered significant livestock feedstuffs. Because of the significant livestock feedstuffs for cowpea, the Agency requires a feeding study in order

to determine the dietary burden associated with cowpea. Because an appropriate feeding study has not been submitted for fenamidone, cowpea has been excluded from the tolerance in or on bean, succulent.

V. Conclusion

Therefore, tolerances are established for residues of fenamidone, 4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-, (S)-, in or on bean, succulent, except cowpea at 0.80 ppm; ginseng at 0.80 ppm; onion, bulb, subgroup 3-07A at 0.20 ppm; and onion, green, subgroup 3-07B at 1.5 ppm. This regulation additionally removes established tolerances at 0.20 ppm in or on garlic; garlic, great headed; onion, bulb; and shallot, bulb. Finally, this regulation removes established tolerances at 1.5 ppm in or on leek; onion, green; onion, welsh; and shallot, fresh leaves.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under

Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 28, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.579:

a. Remove the commodities “Garlic”; “Garlic, great headed”; “Leek”; “Onion, bulb”; “Onion, green”; “Onion, welsh”; “Shallot, bulb”; and “Shallot, fresh leaves” from the table in paragraph (a)(1).

- b. Add alphabetically the following commodities to the table in paragraph (a)(1).

The amendments read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Bean, succulent, except cowpea	0.80
* * *	* *
Ginseng	0.80
* * *	* *
Onion, bulb, subgroup 3-07A	0.20
Onion, green, subgroup 3-07B	1.5
* * *	* *

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